

## **REMARKS**

Claim 27 is currently pending with claims 1–26 and 28–46 canceled without prejudice or disclaimer. Claim 47 is added by this paper.

### **Claim Amendments**

Claim 27 has been amended. Support for the amendment can be found at page 10, line 2 of the instant specification. The amendments do not recite new matter.

### **Rejections under 35 U.S.C. § 112, first paragraph (written description)**

Claim 27 has been amended as per the Examiner's suggestion. This is not an acquiescence to the grounds of the rejection, nor a change to the scope of the original claims, but amends claim directed to subject matter disclosed in the originally filed application.

It is respectfully submitted that the pending rejection is moot in view of the amendments. The Examiner is courteously requested to withdraw the rejection.

### **Rejection under 35 U.S.C. § 112, second paragraph (enablement)**

Claims 35–46 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly being non-enabled. The rejection is now moot in view of cancellation of these claims. Withdrawal of the rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 103 (a)**

Claim 27 stands rejected under 35 U.S.C. § 103 (a) as being unpatentable over Stoppelli et al. (*PNAS*, vol. 82, pages: 4939–4943, 1985) in view of Inamura et al. (US 5,874,254). Additionally, claim 27 stands rejected under the same provisions as being unpatentable over Li et al. (US 6,638,502). Applicants traverse both of these rejections.

Stoppelli teaches a purified amino-terminal fragment (ATF) of human urokinase plasminogen activator comprising amino acid residues 1–135, which is capable enhancing the differentiation of monocytes in culture despite being devoid of catalytic activity. See the “Introduction” of Stoppelli et al. The cited reference does not teach or suggest an anti HIV-1 pharmaceutical composition for injection. In addition, Stoppelli does not teach or suggest a fragment consisting amino acids 21–155 of the prepro-urokinase (sc-uPA). See amended claim 27 and claim 48. Applicants respectfully submit that the binding/affinity studies and differentiation assays of Stoppelli would be insufficient to motivate or guide one of ordinary skill in the art to (a) use the claimed polypeptides as an anti-viral agent and/or (2) reformulate a composition comprising the claimed polypeptide(s) which also encompasses all the structural and functional limitations recited in Applicants' claim 27. Furthermore, since Inamura's disclosure on compositions comprising Fibroblast growth factor-5 (FGH-5) (see the Abstract and Background sections of Inamura et al.) is silent as to the use of sterile aqueous or non-aqueous solvents with the claimed polypeptides (e.g., cleavable polypeptides), nothing in the teachings of either Stoppelli or Inamura would sufficiently guide or motivate one of ordinary skill in the art to combine the cited teachings and reformulate a composition claimed by the instant invention. The cited references, either solely or in combination, cannot render obvious what is claimed by the instant invention. Withdrawal of the rejection is respectfully requested.

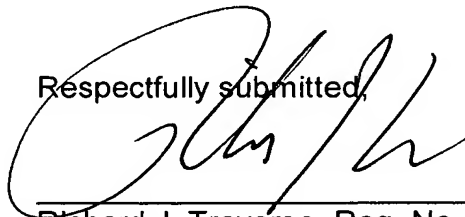
Regarding Li's disclosure, Applicants respectfully submit that the reference is directed to a *method* of inhibiting tumors comprising administering a gene encoding an amino terminal fragment of urokinase that comprises an EGF-like domain. See the Abstract and claim 1 of Li et al. The compositions (nucleotides vs. polypeptides), pharmacological targets (tumors vs. HIV-1), and the methods (gene-therapy vs. pharmaceutical preparation) of Li et al. do not encompass what is claimed by the instant invention. See Applicants' amended claim 27 and claim 47. As such, Li et al. cannot render obvious what is claimed by the instant invention. Withdrawal of the rejection is courteously requested.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the

Examiner is courteously invited to telephone counsel at the number indicated below.

No fees are believed to be due with this response; however, the Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Traverso', is written over a horizontal line.

Richard J. Traverso, Reg. No. 30,595  
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO  
& BRANIGAN, P.C.  
Arlington Courthouse Plaza 1, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
Telephone: (703) 243-6333  
Facsimile: (703) 243-6410

Attorney Docket No.: **HAYAK-0009**

Date: August 7, 2006